IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:
Martin L. LENHARDT

Confirmation No.: 8595

Serial No.: 09/822,841

Art Unit: 3737

Filed: April 2, 2001

Examiner: Qaderi, Runa S.

For: TINNITIS MASKER/SUPPRESSOR

NOTICE UNDER 37 C.F.R. § 1.612 FOR LIMITED ACCESS TO DECLARATION PURSUANT TO 37 CFR §1.131

Dear Sir:

Notice is hereby given that the attached Declaration under 37 C.F.R. § 1.131 by Dr. Martin L. Lenhardt, is being filed under the limited access provisions of 37 C.F.R. § 1.612. Accordingly, the aforementioned Declaration is available for inspection by an opposing party only after the preliminary motions under 37 C.F.R. § 1.633 are decided.

Respectfully submitted,

Date: 1-15-04

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Customer No. 26633

Attorney Docket No. 38025-0030

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	Group Art Unit: 3737
Martin L. LENHARDT	:	
App. No.: 09/822,841	:	Examiner: Qaderi, Runa S.
Filed: April 2, 2001	:	
Title: TINNITIS MASKER/SUPPRESSOR		

Commissioner for Patents
P.O. Box 1450
Washington, DC 20231

Sir:

Declaration under 37 C.F.R. §1.131

I, Martin L. Lenhardt, am the inventor of the invention disclosed and claimed in the above-referenced patent application.

I conceived and actually reduced to practice a method and system for treating tinnitus in which an input sound in an upper range is multiplied with an ultrasound frequency and recorded on a recording medium for later playback prior to February 5, 2001, and therefore prior to the filing date of PCT application number PCT/US02/03866 to Viirree, et al. as evidenced by the documents attached hereto. All masked-out dates are prior to February 5, 2001.

Under my direction, tests were performed in the United States to determine the effectiveness of treatments using embodiments of my invention. These tests were performed as part of a research effort, a print out of the proposal for which is attached as Exhibit A. I finished drafting that proposal and submitted it to my employer, Virginia Commonwealth University, prior to February 5, 2001.

Referring to Exhibit A, on page 7 of that proposal, I described the concept for modulating speech with a carrier between 10 and 15 kHz, demonstrating that I had conceived of this prior to February 5, 2001. Further, on page 14, I described the concept of modulating music with a carrier between 10 and 15 kHz, demonstrating that I had conceived of this prior to February 5, 2001. Further, on pages 19 and 20, I described an alternative treatment of tinnitus

App. No. 09/822,841 Attorney Docket No.: 38025-0030

consisting of modulating stereo music with ultrasound between 10-20 kHz and ultrasound above 20 kHz, demonstrating that I had conceived of this prior to February 5, 2001.

The test equipment I used in the aforementioned tests is illustrated in the picture on the presentation slide that is Exhibit B. I prepared this presentation slide prior to February 5, 2001. These photographs demonstrate that I had reduced to practice the concept of modulating music with ultrasound to use as a treatment for tinnitus prior to February 5, 2001.

I prepared the presentation slide that is Exhibit C prior to February 5, 2001. This slide illustrates the system configuration of a CD player directly providing the input to a piezo amplifier connected to the output device. This slide demonstrates that I had conceived of the invention of recording the modulated sound, such as music, on a compact disc to eliminate the need for an ultrasound source and modulator from the system for treating tinnitis prior to February 5, 2001.

Exhibit D is a photograph of CDs that were prepared at my direction on which were recorded tinnitus treatment signals. Three of the CDs were recorded prior to February 5, 2001. As the labels written on the CDs show, the recorded tinnitus treatment signals comprise a tone modulated with music. This image demonstrates that I had reduced to practice the invention of recording tinnitus treatment signals on CDs prior to February 5, 2001.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above identified application or any patent issued thereon.

Martin L. Lenhardt

Date: January 13 2004

Sound Technique Systems, LLC
in association with
General Medical Industries, Inc.
at the Virginia Biotechnology Research Park
800 East Leigh Street, Lab 54
Richmond Virginia 23219-1534

Research Application Renewal:

[redacted] – March 31, 2001

Titles: The development of an acoustic based method for measuring fluid pressure/volume in the human head.

The development of additional devices for hearing, tinnitus and bodily vibration.

Principal Investigator: **Martin l. Lenhardt, Ph.D., Au.D.**
Professor of Biomedical Engineering
Virginia Commonwealth University
Box 980168 MCV
Richmond, VA 23298-0168

Institutional Officer: **Herbert B. Chermside, CRA**

Signature____

Contents

Budget STS Proposal:

1.	Name	Virginia Commonwealth University
2.	Address	Richmond VA 23209
3	Location **OFF CAMPUS** Effort	800 E. Leigh St. lab 54 Richmond, VA 23219 710 Denbigh Blvd Newport News, VA 23608
4	Titles	The development of and acoustic based method for measuring fluid pressure/volume in the human head. The development of additional devices for hearing, tinnitus and bodily vibration.
5	PI	Martin L. Lenhardt, Ph.D., Au.D.
6	Position	Professor of Biomedical Engineering
7	Post doctoral student	$30,000
8	Laboratory space Research Park 719 Denbigh Blvd NN 1400 Key Blvd Consultants Mr. A. Madsen Dr. R. David Dr. Tim Cameron Dr. J. Genova H. Neal, MS	 $17,000 10,000 20.000 65,000 software/firmware 25,000 neurology 18,100 sensor engineering 25,000 physics 15,000 FDA applications

VCU budget

Ultra Pitch^tm

Ultra Pitch^tm

High frequency emphasis listening device

A new device using patented technology

Hearing loss can seriously compromise speech perception particularly in high-level background noise. High frequency hearing loss translates into more than just a loss in sensitivity, but a loss in analysis and the ability to adequately process any high frequency sound. Individuals with high frequency loss have the common experience is that something is missing in their listening.

No electronic device, no mater how sophisticated, can completely restore lost hearing. It is possible to use a new proprietary bone conducted vibrational delivery system to accent the remaining high frequency receptors in the ear and in the brain and to recruit them into contributing to a unique sense of high pitch and timbre necessary for speech and environmental sound fidelity

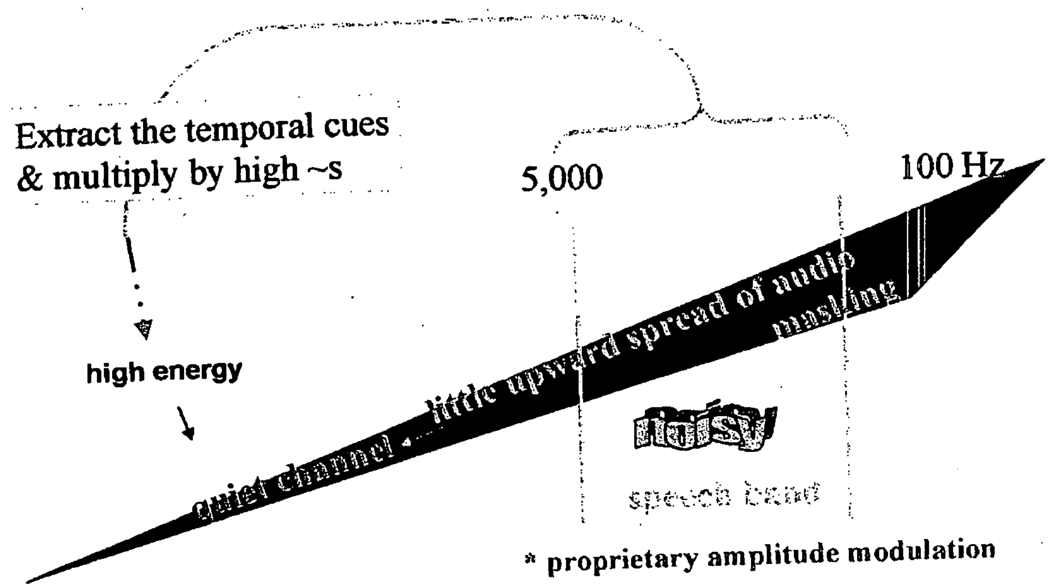
The Ultra Pitch, because of its unique form of stimulation results in:

1. high frequency pitch resistant to air conduction ambient noise,
2. reprogramming of cortical neurons and improved perception with time.

The technique of creating high frequency speech is depicted in the figure below. Natural speech or speech is through a high pass filter, is multiplied by a carrier in the 10-20 kHz range. The signal is then presented to the skin of the head or neck as vibration, typically conceived of as bone conduction hearing. This is absolutely necessary to achieve the sense of high pitch perception

The signal can be presented in a number of different formants. Typically speech is presented with the carrier suppressed. If both sidebands are present the signal is termed double sideband modulation. If only one sideband is present the signal is termed signal sideband modulation. If only the upper sideband is present, it is termed upper sideband modulation. Currently double and upper sideband modulated speech schemes are available on the fully digital Ultra Pitch

speech spectrum envelope multiplied by high audiofrequency carriers*



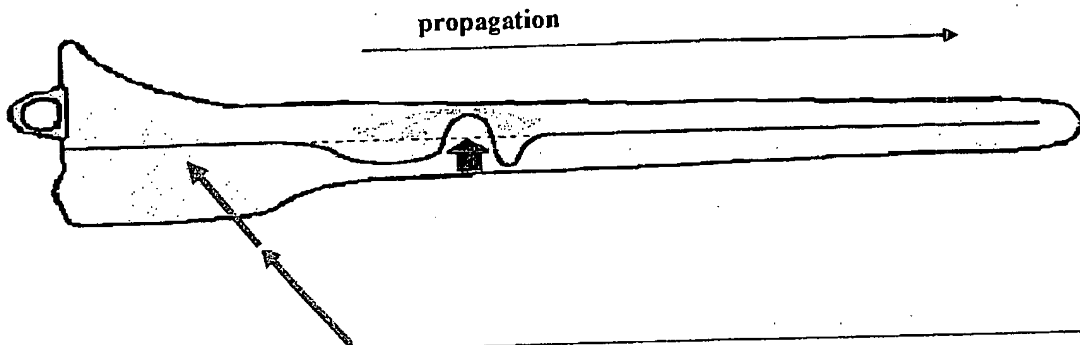
* proprietary amplitude modulation

The anatomical and physiological factor

Many insults can permanently damage hair cells and result in a loss of hearing sensitivity. In the cases of persistent deafness, cortical neurons tuned to the region of inner ear loss will reprogram such that sensitivity is shifted to a lower frequency. With progressive peripheral loss reprograming in the cortex shifts the "hearing range" or neural tuning of cortical cells, lower and lower in frequency. Individuals with high frequency hearing loss are thus faced with more than just loss of sensitivity but also brain reorganization that may restrict speech perceptual abilities previously performed effortlessly. In fact the brain reorganization may be far more intrusive into their lives than the peripheral loss.

Cortical reorganization can work in reverse. That is an increase in high frequency stimulation should reverse the loss of high frequency neurons. This is supposition, but is logical since frequency discrimination training in monkeys does increase neuronal representation in the trained frequency area.

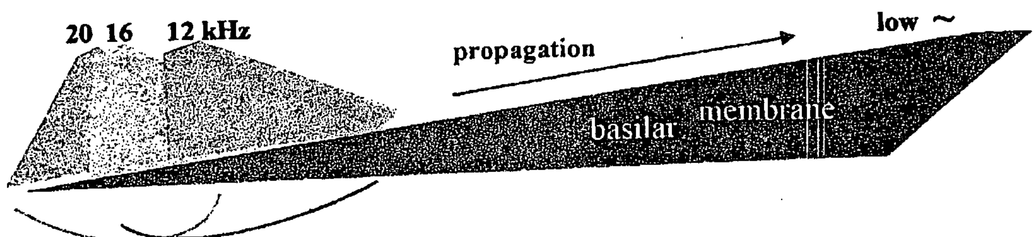
From Rauschecker, September 1999 *Science*



High frequency hearing loss triggers reorganization of high frequency auditory cortex.
Lack of stimulation is thought to be key factor.
Area effected is a function of degree of high frequency deprivation. High frequency speech may expand cortical representation of higher frequencies.

mechanical and neural tuning accounts for high frequency transduction

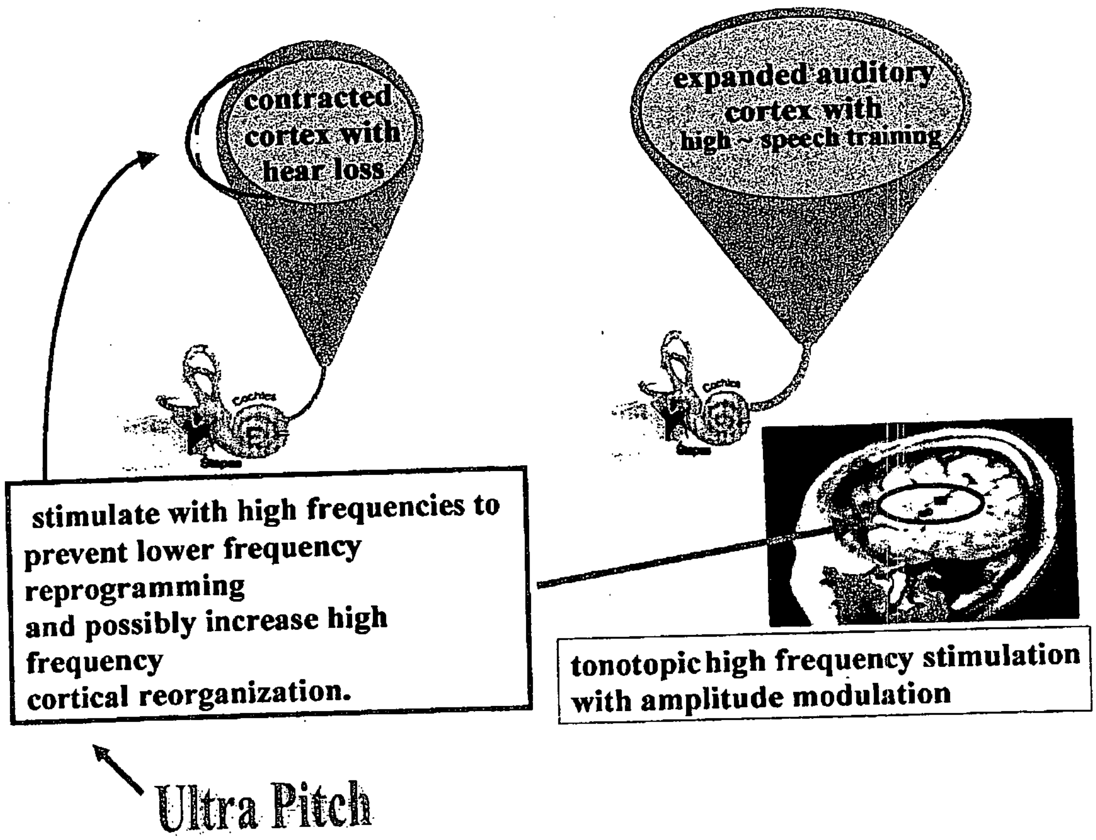
overlapping mechanical tuning



overlapping neural tuning

Result : poor place specificity
adequate temporal coding

A restriction in the amount of high frequency information coded in the cochlea and subsequently fed to the cortex has a profound effect on the function of cortical neurons. Without stimulation, high frequency neurons reprogram to lower frequencies. The end result is a shrinking population of neuron sensitivity to the high frequency vocal harmonics. As a result people can not function as they once did. The following graphically illustrates the ear brain connection.



The recent work of Hosoi et al, 1998 (Lancet, copy enclosed) demonstrated that audiofrequencies multiplied on high frequency carriers, as with the Ultra Pitch, stimulate the high frequency regions of the primary auditory cortex. This is precisely the cortical area affected with high frequency hearing loss.

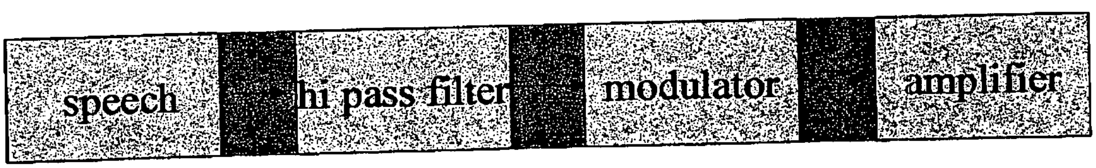
Three key points:

1. High frequency hearing loss results in reorganization of the primary auditory cortex such that high frequency neurons lower their tuning thus adding a component of cortical deafness.
2. A new patented high pitched device may provide assistance by stimulating the remaining high frequency area of the inner ear without notable distortion and no audiofrequency feedback. The transducer radiates little energy into the air hence the Ultra Pitch can be used discretely.
3. Ultra Pitch is a hearing aid supplement, a channel to introduce high frequency stimulation not possible by air conduction.

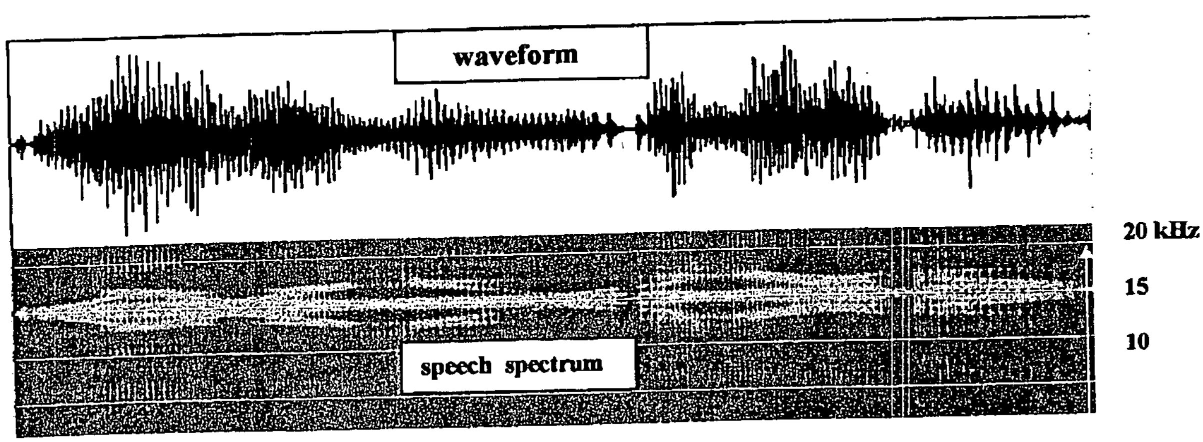
Ultra Pitch^{tm}

The concept behind ultra pitch is to take the envelope of speech, high pass filter it and multiply it by a carrier between 10 and 15 kHz and present the signal as vibration to the skin of the head or neck. The approach allows considerable amplification, with little envelope distortion. High frequency energy at sufficient energy will drive the inner ear at it highest possible frequency response. This is typically about half an octave above the highest frequency perceived conformably by air conduction. It is well known that at high intensities the frequency response of ear structures increases.

The scheme of the Ultra Pitch is depicted below:

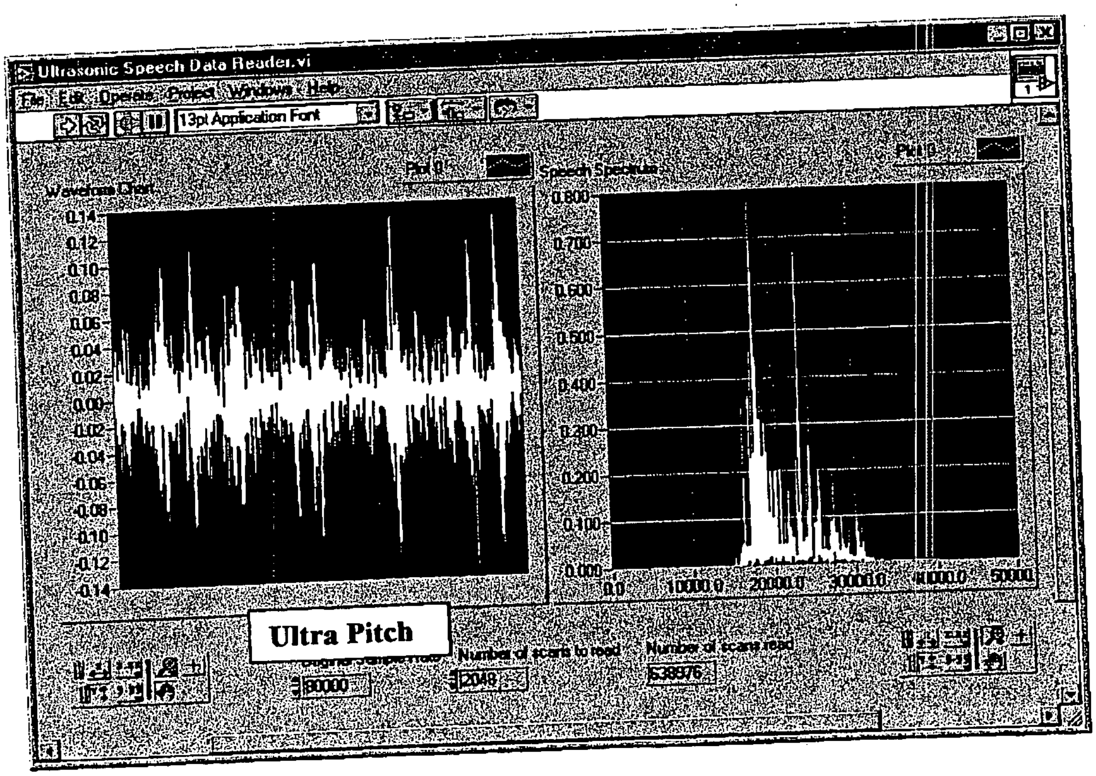


An example of musical energy multiplied by a 15 kHz carrier (carrier suppressed double sideband) is presented below. Note the undistorted waveform and the spectrum shift to 15 kHz.



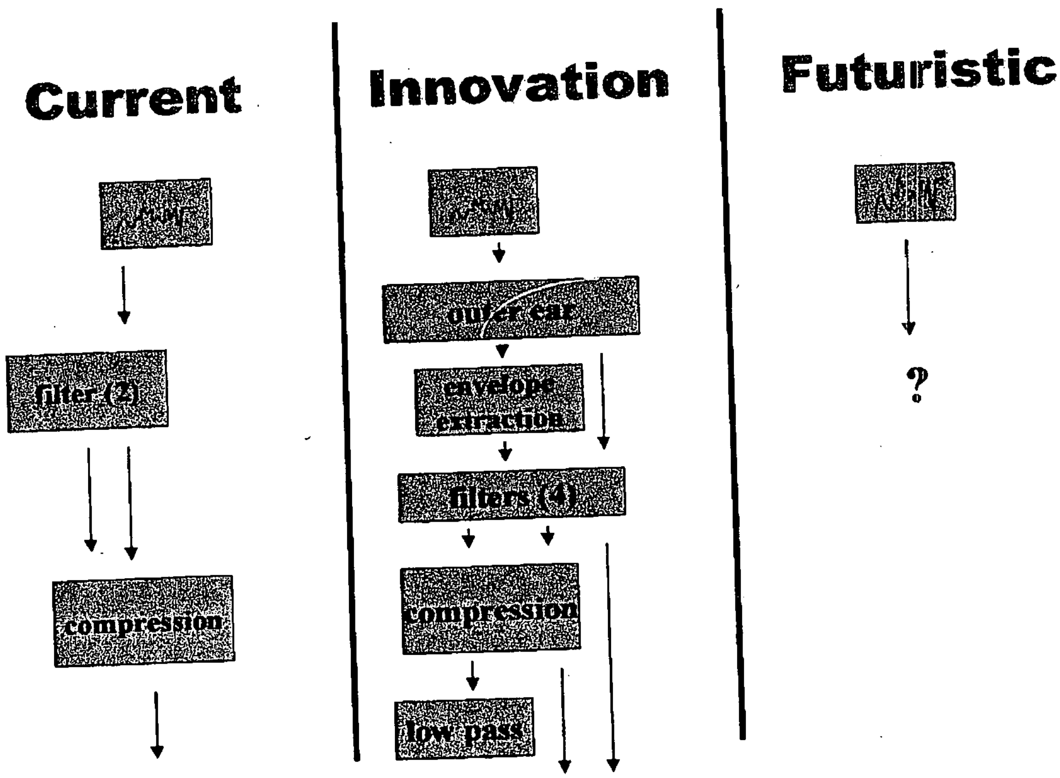
There are a number of digital signal processing schemes available. The prototype is developed on a DSP card with an amplifier and high frequency skin transducer. The Ultra Pitch device has two channels, one for conventional listening the other for the proprietary modulated vibration.

The suggest manner of use is to play the "unprocessed" musical piece in one ear (or in stereo) and play the filtered and amplitude modulate version through a skin traducer affixed to the skin of the head or neck. The perception will be a fused image with high frequency augmentation that should provide an increased awareness of the treble elements in music or voice. The following is a print of speech, high passed filtered (2 kHz) upper sideband modulated with a 15 kHz suppressed carrier. Note the clean waveform.



What is needed

The current device is a single channel demonstration version. Two types of filtering have been shown to augment vowel and consonant perception respectively. Other algorythms need to be developed to increase speech fidelity. Some possible innovations are depicted below.



Ultra Pitch[tm]

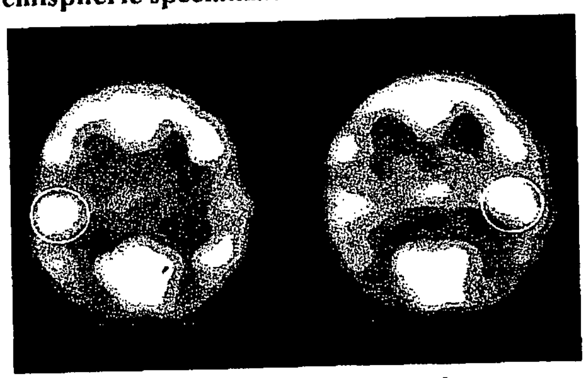
Ultra Pitch[tm] for musicians
High frequency emphasis listening device for musical retraining

A new device using patented technology

Hearing loss can seriously compromise speech perception and to a lesser degree music perception in those untrained as musicians. Language is processed in the left hemisphere in the vast majority of right handed individuals while music is a right hemispheric function. However those trained in music theory the left brain becomes essential. For musicians, high frequency hearing loss translates into more than just a loss in sensitivity, but a loss in analysis, synthesis, creativity and the ability to generalize the individual internal representation of music to the audience at large. The common sense is that something is missing.

No electronic device, no mater how sophisticated, can restore lost hearing. It is possible to use a new proprietary bone conducted vibrational delivery system to accent the remaining high frequency receptors in the ear and in the brain and to recruit them into contributing to a unique sense of musical high pitch and timbre.

Brain scans of hemispheric specialization in musicians and non-musicians



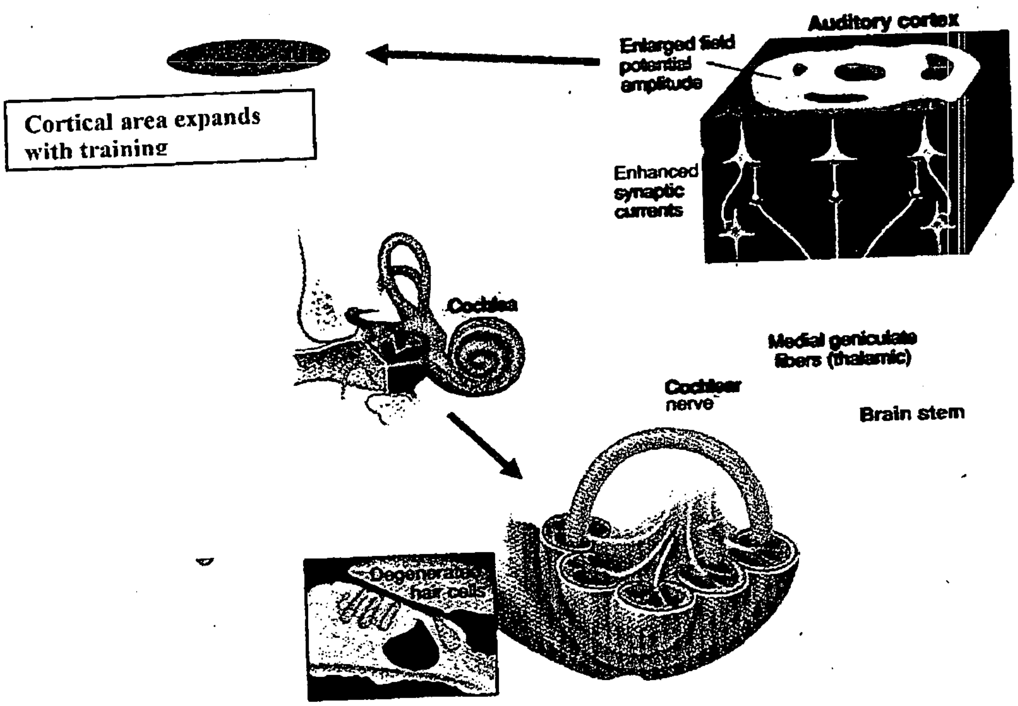
Non-musicians	**language**	**music**
Musicians	**language & music**	**some music**

The anatomical and physiological factor

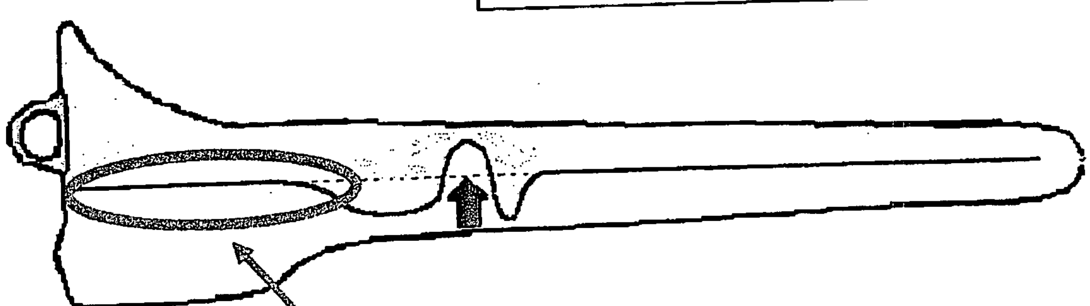
Intense sound, including music can permanently damage hair cell and result in a loss of hearing sensitivity. In the cases of persistent deafness, cortical neurons tuned to the region of inner ear loss will reprogram such that sensitivity is shifted to a lower frequency. With progressive peripheral loss reprograming in the cortex shifts the

"hearing range" or neural tuning of cortical cells, lower and lower in frequency. Musicians are thus faced with more than just hearing loss but brain reorganization that may restrict musical abilities previously performed effortlessly. In fact the brain reorganization may be far more intrusive into their professional careers than the peripheral loss.

Cortical reorganization first occurs as a result of training and learning.

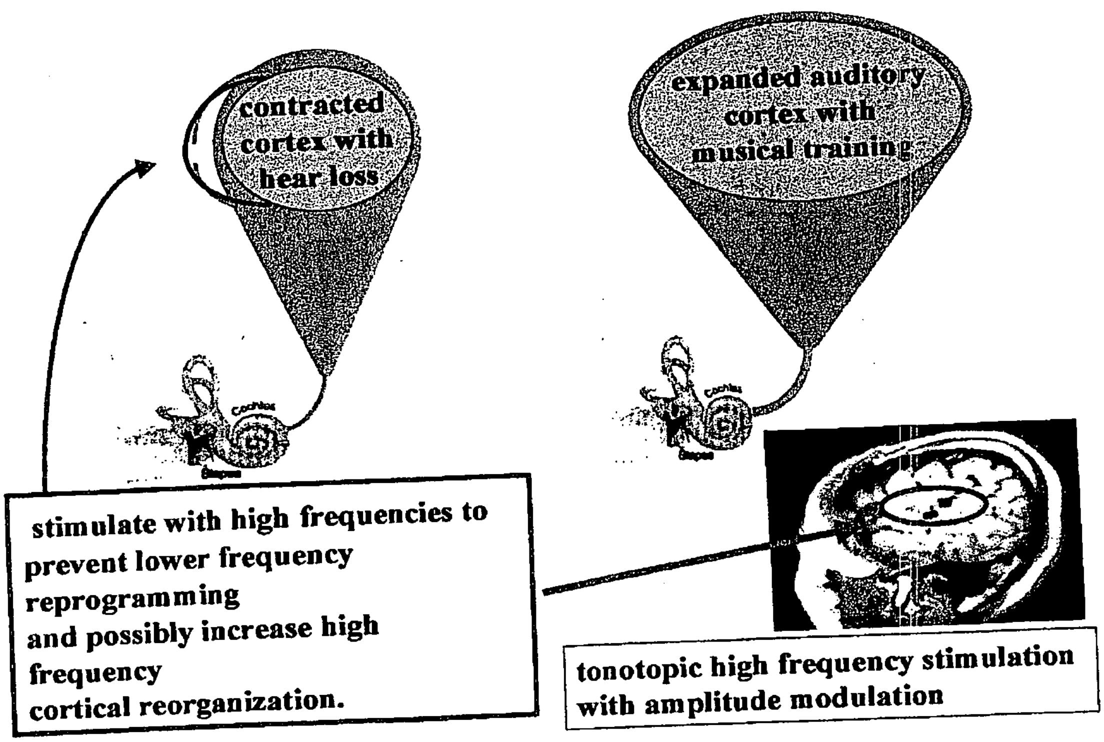


From Rauschecker, September 1999 *Science*



High frequency hearing loss triggers reorganization of high frequency auditory cortex.
Lack of stimulation is thought to be key factor.
Area expanded as result of musical training now shrinks as a function of degree of high frequency deprivation.

A restriction in the amount of high frequency information coded in the cochlea and subsequently fed to the cortex has a profound effect on the function of cortical neurons. Without stimulation, high frequency neurons reprogram to lower frequencies. The end result is a shrinking population of neuron sensitivity to the high frequency harmonics of musical instruments and voice. As a result professional musicians can not function as they once did, even after all the years of training and practice. The following graphically illustrates the ear brain connection.



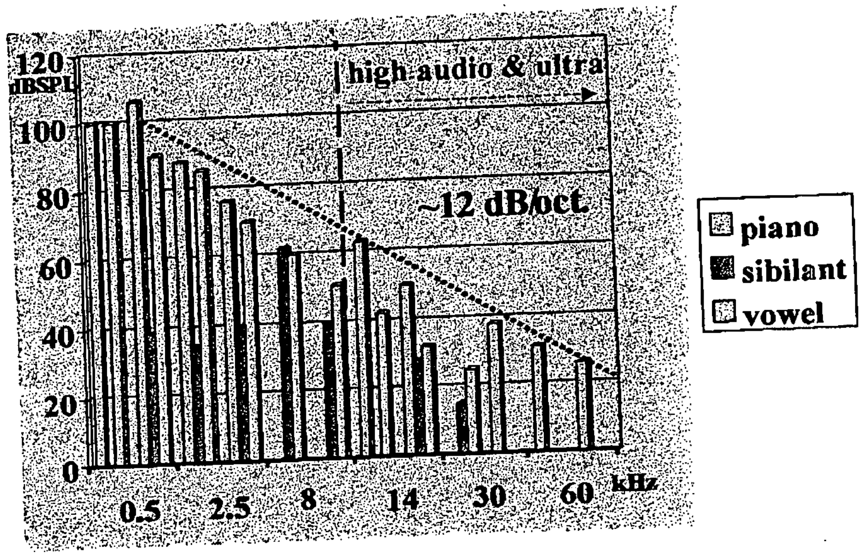
Ultra Pitch for musicians

The recent work of Hosoi et al, 1998 (Lancet, copy enclosed) demonstrated that audiofrequencies multiplied on high frequency carriers, as with the Ultra Pitch, stimulate the high frequency regions of the primary auditory cortex. This is precisely the cortical area affected with high frequency hearing loss.

High frequency hearing is necessary in music because both harmonic, non-harmonic instruments and voice have significant acoustic energy above 10 kHz which influence the quality of perception and has been shown to alter listeners EEG (Oohasi et al, 1997). Perhaps the most compelling evidence is that musician with high frequency hearing loss readily report some degree of functional impairment. Below is graphic evidence of the

high frequency energy in speech and piano spectra. Trumpets, violins chimes too produce very high frequency energy (Boyk, 1997).

high sonic and ultrasonic musical energy



piano and sung sibilant from Boyk, 1998; vowel from lab

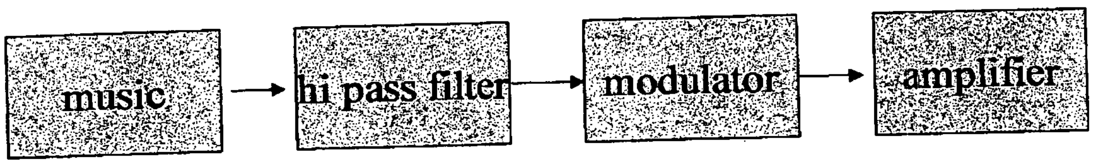
Six points should be made:

1. Musical practice from at least late childhood increases the representation of musical stimuli in the primary auditory cortex. This has been documented in piano notes, which are coded tonotopically across the cortex. The area of increase (in terms of intensity and synchrony) is on the order of 25% above non-musicians (Pantev et al, 1998 *Nature*).
2. Musical instruments and voice have significant acoustic energy in the high audio and ultrasonic ranges, audible under certain conditions (Lenhardt et al, 1991 *Science*).
3. High frequency hearing loss results in reorganization of the primary auditory cortex such that high frequency neurons lower their tuning thus adding a component of cortical deafness.
4. Musicians will not have the same neuro facility with music as before hearing loss, even with some hearing loss due to aging
5. A new patented high pitched device may provide assistance by stimulating the remaining high frequency area of the inner ear without notable distortion and no audiofrequency feedback. The transducer radiates little energy into the air hence the Ultra Pitch can be used discretely.
6. Ultra Pitch is not a hearing aid but rather a listening device for musicians.

Ultra Pitch™ for musicians

The concept behind ultra pitch is to take the envelope of music, high pass filter it and multiply it by a carrier between 10 and 15 kHz and present the signal as vibration to the skin of the head or neck. The approach allows considerable amplification, with little envelope distortion. High frequency energy at sufficient energy will drive the inner ear at it highest possible frequency response. This is typically about half an octave above the highest frequency perceived conformably by air conduction. It is well known that at high intensities the frequency response of ear structures increases.

The scheme of the Ultra Pitch for musicians is depicted below:



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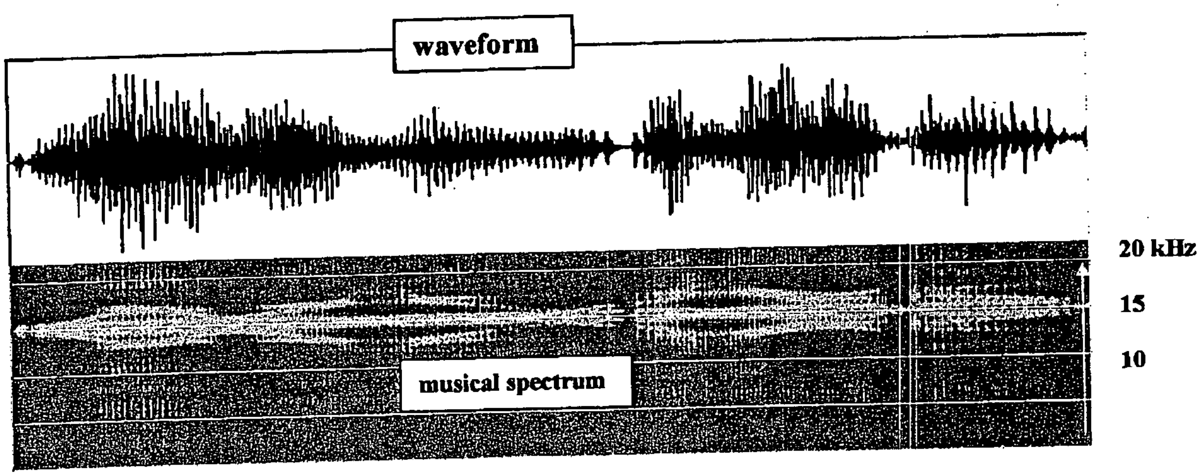
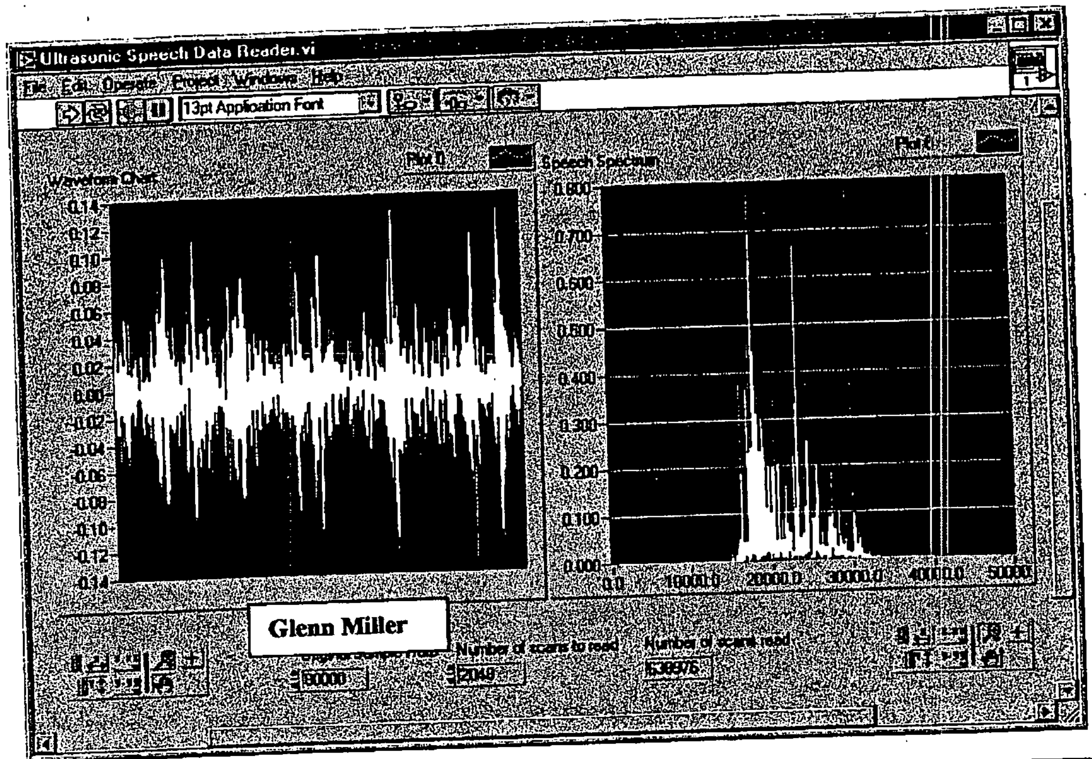


There are a number of digital signal processing schemes available. The prototype is developed on a DSP card with an amplifier and high frequency skin transducer. The Ultra Pitch device has two channels, one for conventional listening the other for the proprietary modulated vibration. The suggest manner of use is to play the "unprocessed" musical piece in one ear (or in stereo) and play the filtered and amplitude modulate version through a skin traducer affixed to the skin of the head or neck. The perception will be a fused image with high frequency augmentation that should provide an increased awareness of the treble elements in music or voice. The following is a print of music, high passed filtered (2 kHz) upper sideband modulated with a 15 kHz suppressed carrier. Note the clean waveform.



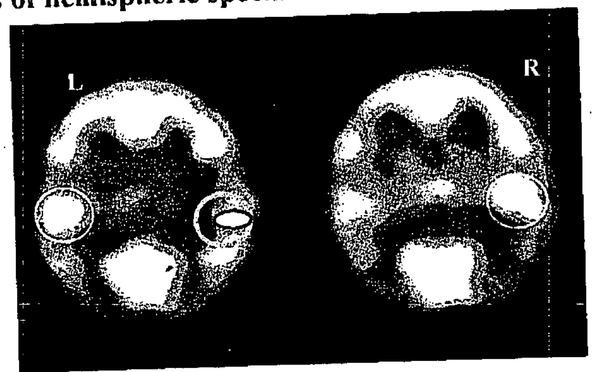
Ultra Quiet^{tm}

Ultra Quiet^{tm} for tinnitus treatment

A new device using patented technology

Tinnitus or ringing due to no known external source is thought to arise in the ear, brain or both. Proponents of the ear theory are encouraged by tinnitus masking with external noise. Critics claim masking is only temporary or marginal at best. Evidence is beginning to mount suggesting a central site of tinnitus. Imaging studies have implicated the primary auditory cortex and limbic structures to be involved in tinnitus.

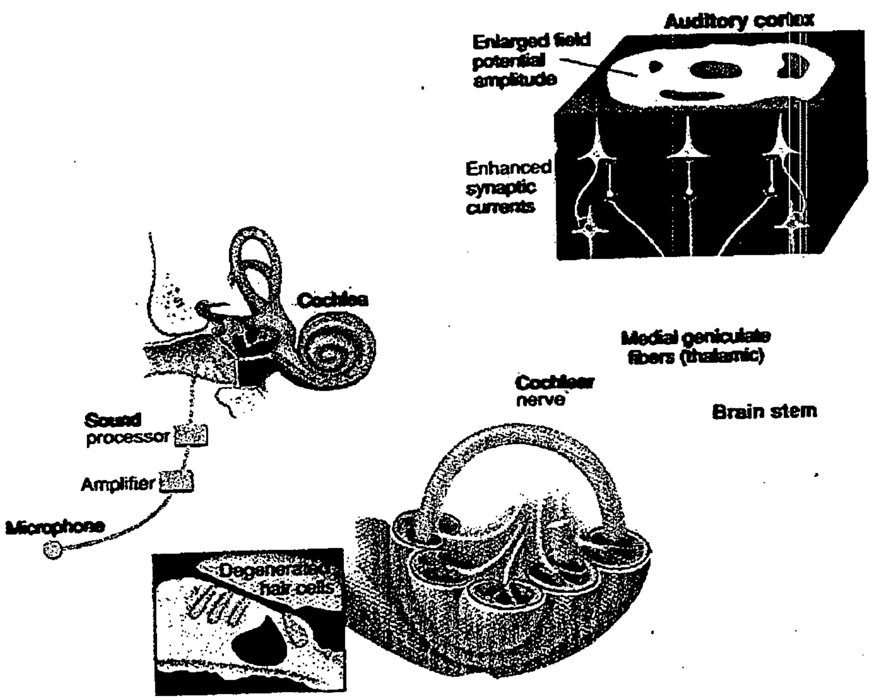
Brain scans of hemispheric specialization in tinnitus patients

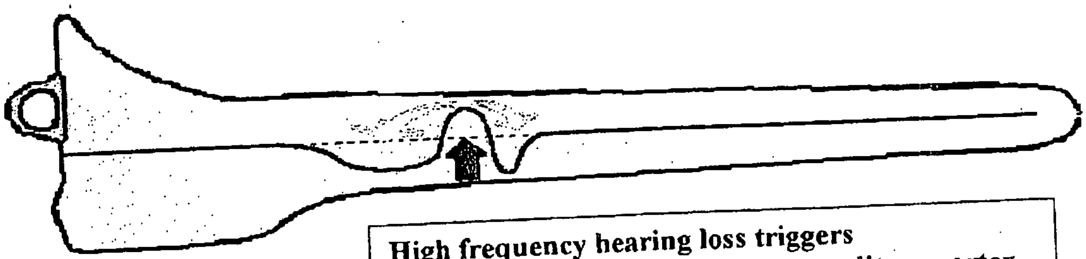


Tinnitus patient **sound in left ear** **tinnitus on the left**

Modified from Lockwood et al, 1998 Neurology

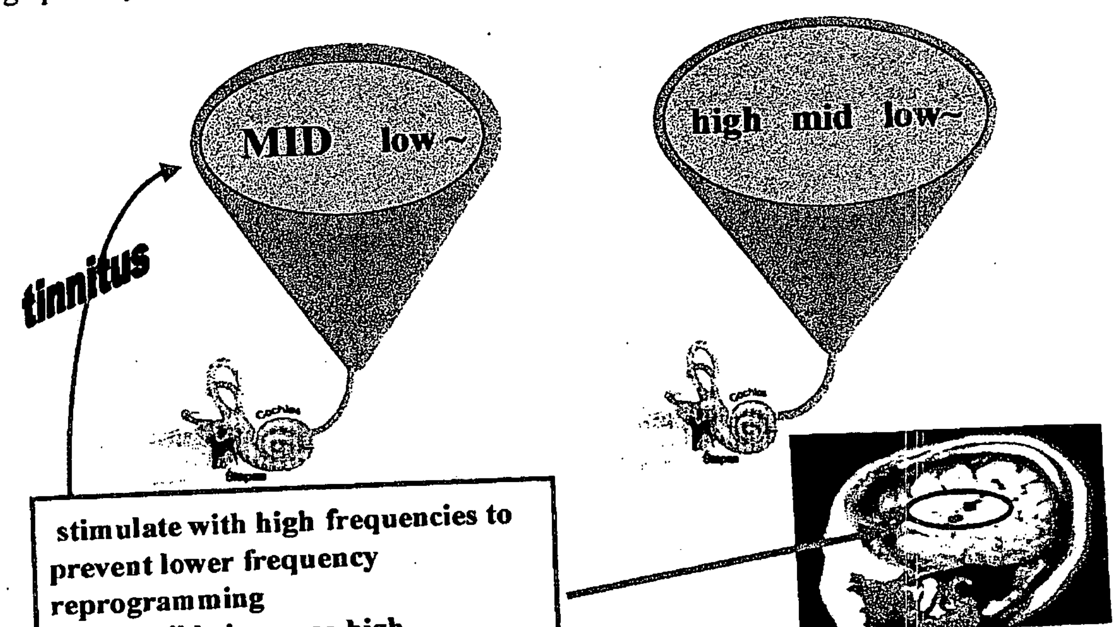
The anatomical and physiological factor
Intense sound, including can permanently damage hair cell and result in a loss of hearing sensitivity. Lockwood et al reported that sound activated a larger are of cortex in tinnitus patients than in matched controls. This "extra" area of cortical stimulation is consistent with the notion that neurons once sensitive to higher frequencies reorganizes and is responses to lower frequencies. Thus there is a greater representation of theses lower frequencies in the cortex following high frequency hearing loss. With progressive peripheral loss reprogramming in the cortex shifts the "hearing range" or neural tuning of cortical cell lower and lower in frequency.





High frequency hearing loss triggers reorganization of high frequency auditory cortex. Lack of stimulation is thought to be key factor. Area expanded as result of musical training now shrinks as a function of degree of high frequency deprivation.

Cortical reorganization first occurs as a result of training and learning and can be seen after cochlear implantation. With electrical stimulation of the auditory nerve there is a restriction in the amount of high information coded in the cochlea and subsequently fed to the cortex has a profound effect on the function of cortical neurons. Without stimulation, high frequency neurons reprogram to lower frequencies. The end result is a shrinking population of neuron sensitivity to the high frequency and the reprogramming process may trigger central tinnitus. Cortical plasticity, that is the invasion of deafferented cortical areas by neural activity from normal cochlea areas. The following graphically illustrates the ear brain connection.



stimulate with high frequencies to prevent lower frequency reprogramming
and possibly increase high frequency
cortical reorganization.

tonotopic high frequency stimulation with amplitude modulation

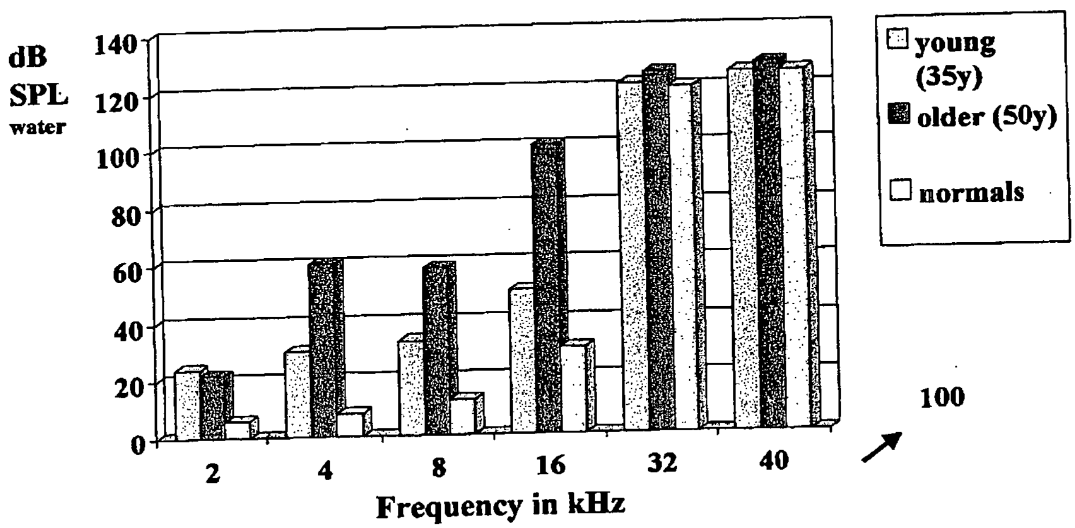
Ultra Quiet for tinnitus

The recent work of Hosoi, 1998 (Lancet) demonstrated that audiofrequencies multiplied on high frequency carriers (40 kHz), as those similar to that of the Ultra Pitch, stimulate the high frequency regions of the primary auditory cortex. This is precisely the cortical area affected with high frequency hearing loss and presumably the site of tinnitus generation.

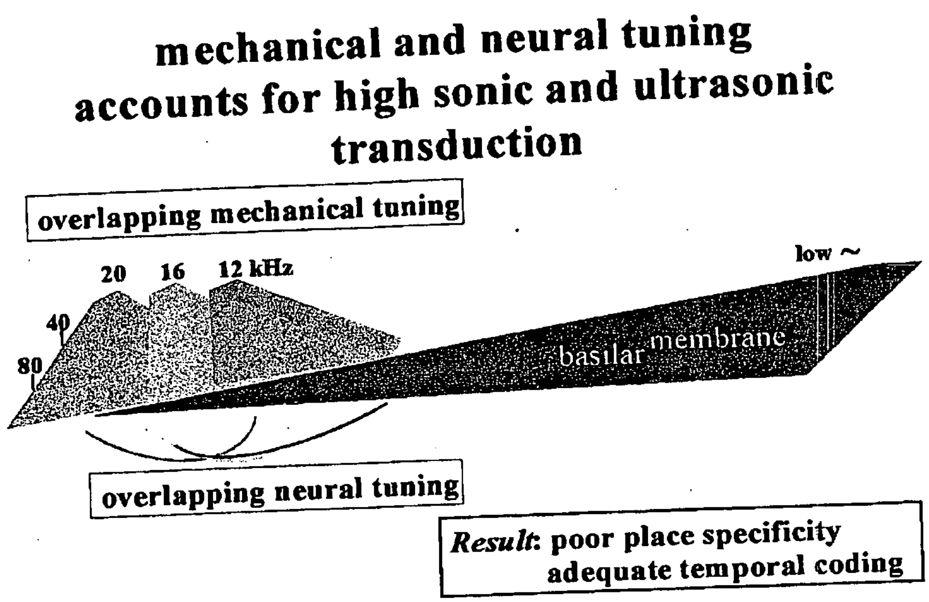
Humans can hear high audiofrequencies and low frequency ultrasonics by bone conduction. The expanded human audiogram is presented below.

Human Hearing

redrawn from Lenhardt et.al., (*Science)* 1991



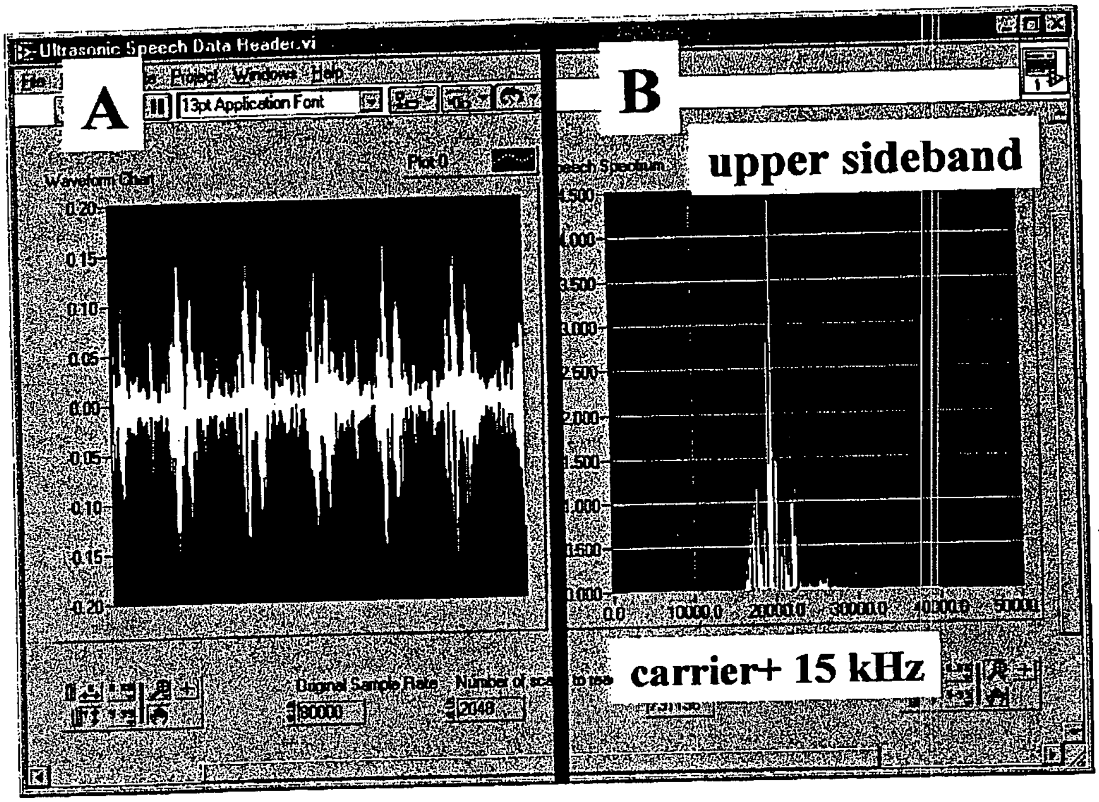
High sonic and ultrasound frequencies are coded in the base of the cochlea. Since the structure is resonant frequencies above resonance will drive the basilar membrane with sufficient vibratory energy. In the case of some with deafness, the saccule is thought to be displaced with high intensity ultrasound.



There are a number of digital signal processing schemes available. The prototype is developed on a DSP card with an amplifier and high frequency skin transducer. The Ultra Quiet device has two channels one for conventional listening the other for the proprietary modulated vibration.

An alternative in the treatment of tinnitus is to couple the tinnitus treatment vibration with music for a more esthetic experience. This is possible by playing stereo music by air conduction and modulating the music such that it becomes the proprietary treatment modality. High sonic noise can be can be substituted for modulated music id preferred. An example of music modulated on a suppressed carrier (and lower sideband) is presented below. Note in panel A, the waveform of music is preserved while the spectrum is shifted above 15 kHz.

ultrasonic music waveform and spectrum



This is a reproduction of the screen on the computer used to produce the digitized music and the digitized music multiplied by a 15 kHz carrier using upper sideband modulation.

Tinnitus treatment modalities

1. **Ultraound**
   (noise or speech/music modulated at frequencies above 20 kHz)
2. **High audiofrequencies**
   (noise or speech/music modulated at frequencies between 10-20 kHz)

Ultrasound is the modality of choice for individuals with severe hearing loss. It must be delivered at intensity levels approximating 5 dB SL (sensation level) for no more than 30 minutes a day.

Meikle et al. 1999 present findings suggesting bone conduction ultrasound using an ultrasonic hearing aid suppressed tinnitus. Eighteen of twenty tinnitus patients

reported ipsilateral suppression and some contralateral suppression. Sixteen reported residual inhibition for one minute after stimulation. Sound Technique Systems now holds the license on the ultrasonic hearing aid for the purpose of tinnitus treatment.

ULTRASONIC HEARING USED IN TINNITUS TRIALS

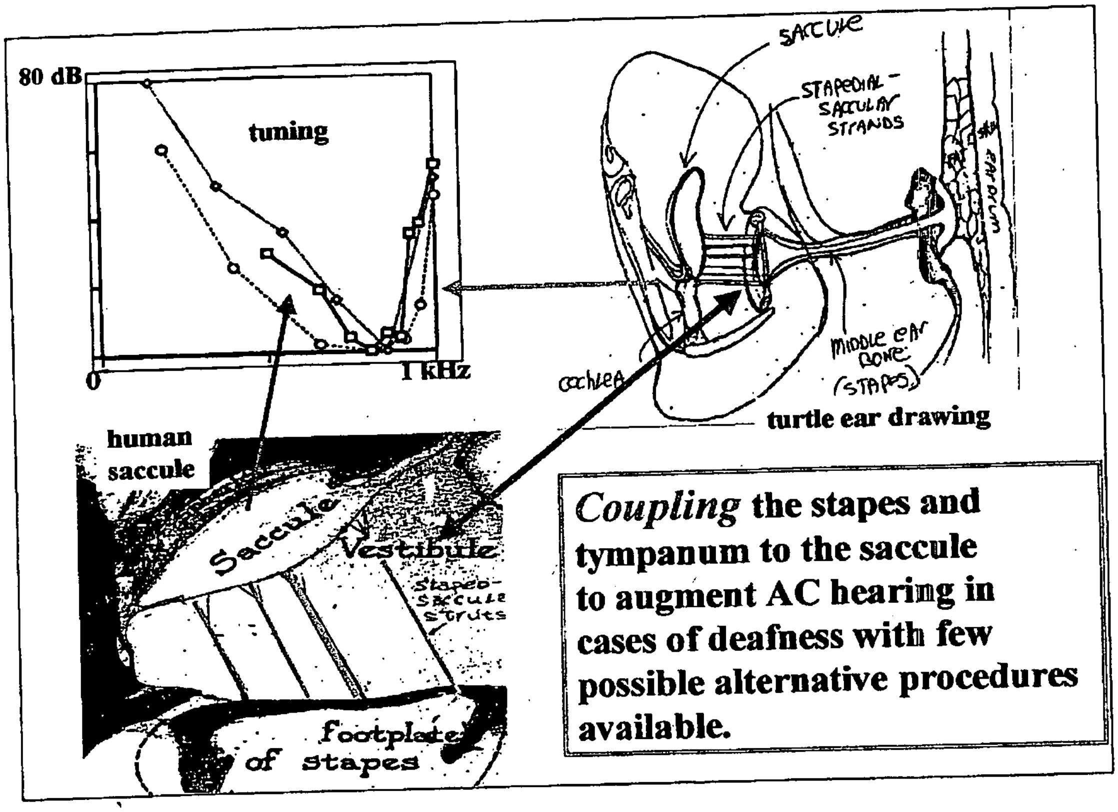
Sound Technique Systems, LLC Richmond

Stapedial Saccular Strut

Otosurgical procedure for the partial remediation of deafness

The strut concept evolved from a study of turtle middle ear anatomy (funding from the American Museum of Natural History). Turtles have an inner ear generally agreed to be primitive and likely similar to that of the stem reptiles. There is genetic evidence that turtles may be more advanced than originally thought. Nonetheless their ear anatomy is a conservative feature for over 200M years. Turtles have a unique connection between their middle ear bone (columella) and the wall of the saccule. I interpret this as a

mechanism to couple the otolith organ with the response of the cochlea. The fibroelastic stapedial-saccular strands of the turtle are depicted in the figure below (upper right).



The stapes footplate in humans is directly opposite the saccule. A procedure has been conceptualized that would allow the insertion of a medical grade silicon strut into the stapes to couple it with the saccular wall. This procedure, if refined, would allow air conducted vibration to act on the otolith organ more efficiently and thus provide an additional channel for speech in ears with compromised inner ear structures in with the vestibule intact (see lower left panel). Some years ago a young lady came to my lab with congenital abnormalities if both inner ears (confirmed on CT scans @NYU and MCV) whom, because of cochlear ossification was not a candidate for an implant. The strut is a potential option for such individuals. In fact any steeply sloping audiogram might indicate the possibility of saccular augmented hearing for better functioning. That is still only a possibility at this stage.

The value of saccular coupling can be seen in a comparison of the tuning curve of a typical auditory fiber from the apex of a mammal, auditory sensitive tuning curve for a mammalian saccular fiber and the hearing range of a turtle. These responses are all relative to the intensity at best frequency, arbitrarily denoted as 0 dB on the ordinate in

the upper left panel of the figure. For all practical purposes these overlap. All are essentially low pass filters. There is a strong likely hood that simultaneous firing of apex cochlear fibers and the tympanum coupled saccular fibers will be synergistic in nature. One should reinforce the other as seen in turtle neurophysiology. The advantage of the strut coupling is energy savings by using the transformer action of the middle to match acoustic impedances. Typically saccular neurons that respond to airborne sound do so at 70-90 dB SPL. The sound actually has to pass through the head. With the strut, responses should be about 25-30 dB SPL. In addition other acceleration neurons with higher frequency responses should also be recruited into firing. Recall the saccule is the auditory organ in some vertebrates (fish ex. herring and most amphibians).

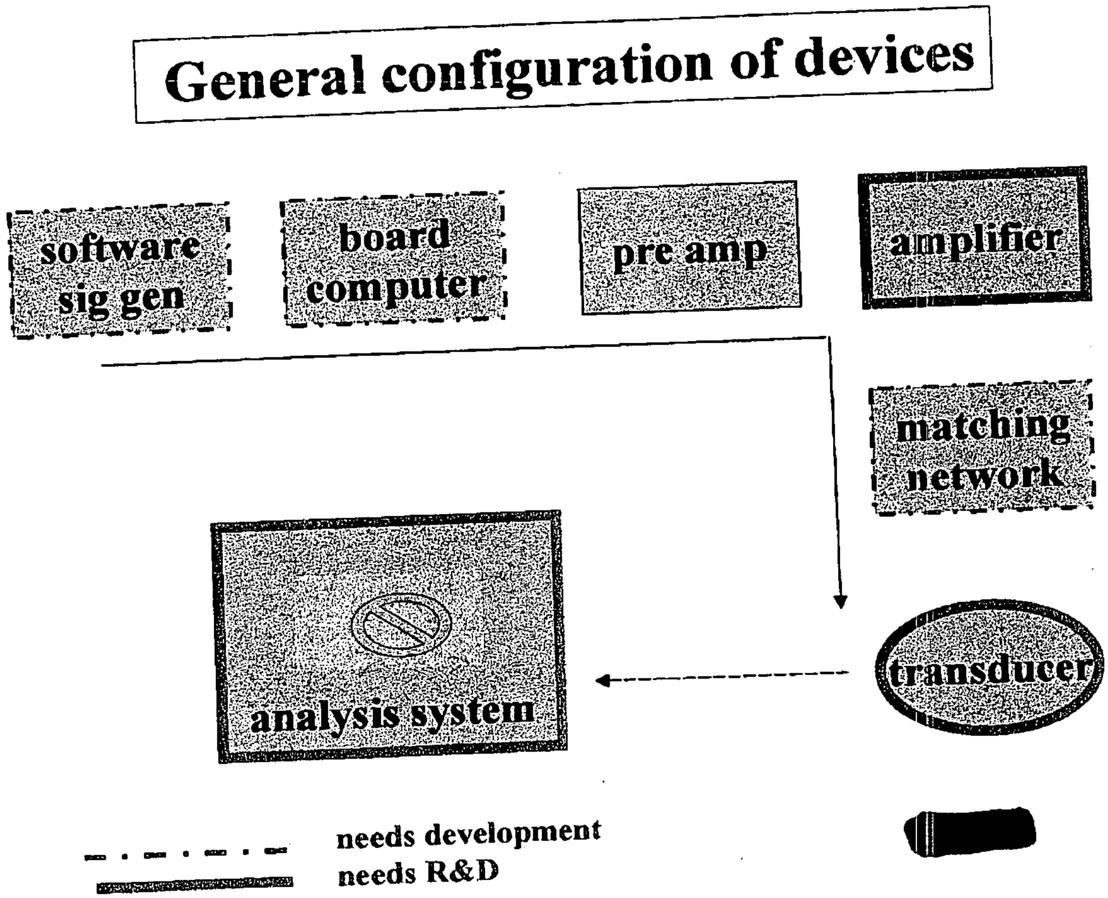
What is needed:

1. Due diligence review at a major otosurgery facility
2. Refinement of the approach and biomaterials suggested
3. Temporal bone assessment to determine practicality

The concept of the strut is simple, use the impedance matching of the middle ear to stimulate auditory neurons in the saccule and possibly recruit acceleration neuron sensitive to audiofrequencies to augment hearing in cases of severe deafness.

Research Plan

The general components of the devices are depicted below. Items highlighted in solid red require continued research and development. Those highlighted in red dashes require more development before implementation. All components are off the self.



All devices share commonality in that the characteristics of the components will be similar. Therefore the thrust of the second year project will be on instrumentation and performance. The goal is to have all ultra audio devices with the same systems architecture. The CSF is more complicated in that there is a sensor and analysis subsystem need.

Perceptual Performance

The UltraPitch and UltraQuiet devices all require acoustical and perceptual performance data. All parameters of carrier frequency and modulation type will be systematically investigated to determine characteristics of optimal performance. The exact methodology will be formulated as the research progresses with the approval of Sound Technique Systems, LLC.

Ultrasonic Tinnitus

Sound Technique Systems has the license on the ultrasonic hearing aid and methods for the purpose of tinnitus management. The license requires $100,000 of research support to Dr. Lenhardt over two years. $50,000 in this proposal is designated toward the development of the ultrasonic tinnitus system. This system will initially be a tabletop design utilizing digital signal processing. Because of the need for rapid processing time and high frequency (20-50 kHz) response 96kHz DSP A/D converters are required. It is the intent of the investigators to modify a DSP board with the higher speech A/D converters necessary that will allow for the ultrasonic frequency generation. Transducers in the low ultrasonic frequencies will have to be developed along with a suitable amplification system.

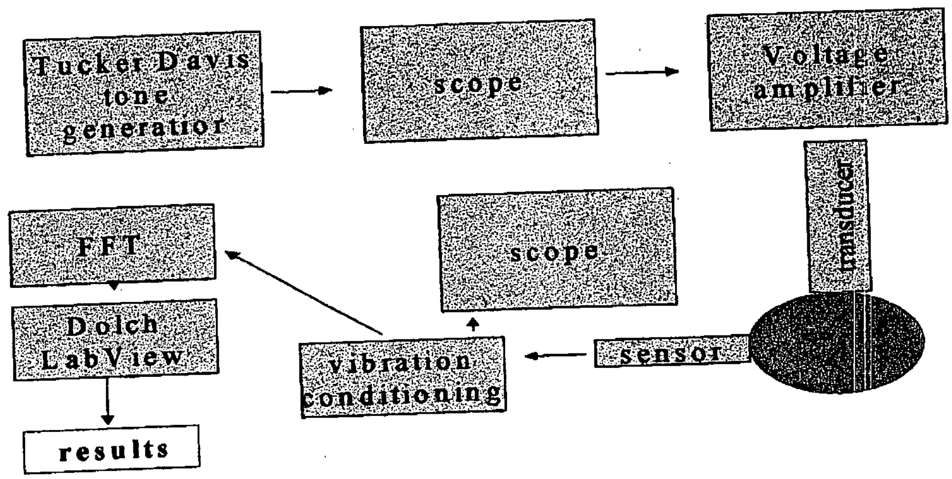
Cerebral Spinal Fluid Device

The CSF research has progressed to the point of operationally defining the acoustic parameters of skull/brain stimulation using modeling and direct measurement. The stimulus/response system must be fully incorporated into a digital system capable of clinical trials in the future. The specific aim of this component of the project is to develop a "within a computer" CSF device, including appropriately biocompatable human interfacing.

Prototype Evaluation

The first laboratory version of "the monitor" was a configuration of generating and analysis gear to demonstrate the concept. That version is depicted in the diagram below.

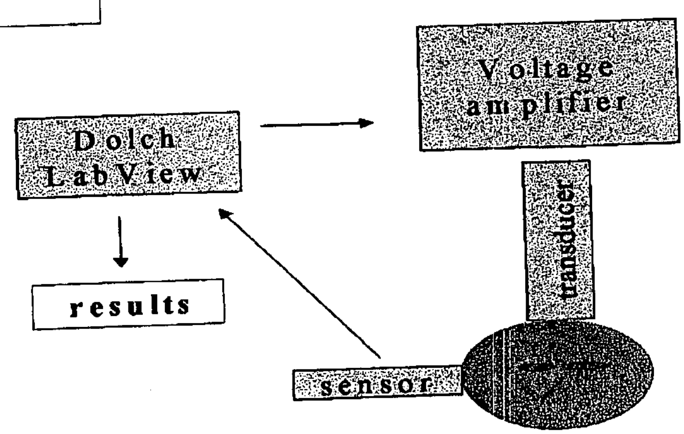
Initial set-up



In stage 3 stimulus generating and response analysis algorithms were developed which now allows for a simpler experimental set-up. This is depicted below.

Prototype set-up

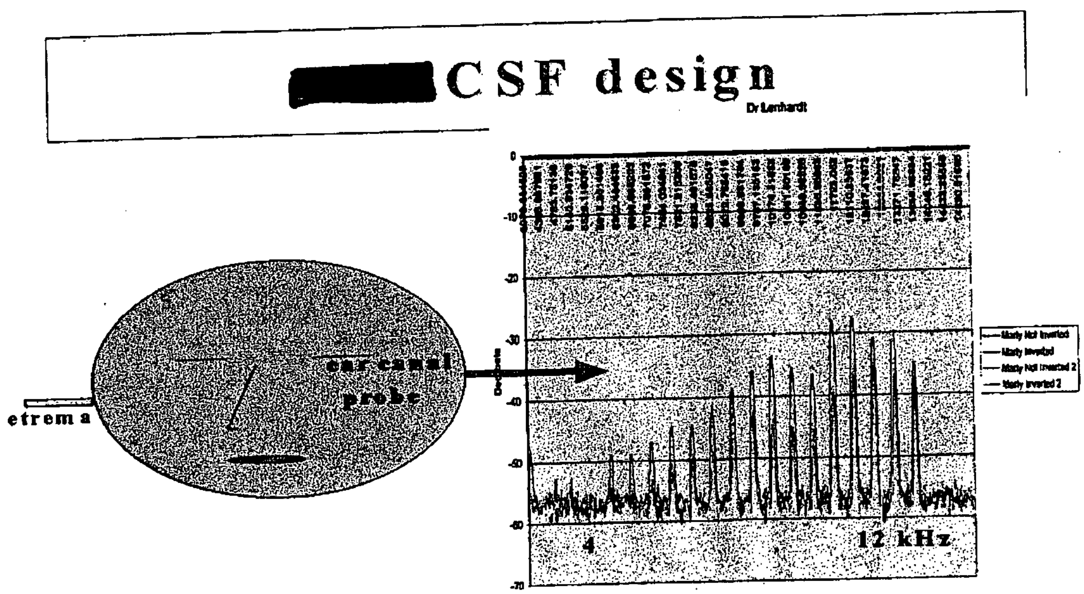
[redacted]



The recording sensor on the head can be any form of vibration pick-up. To date three types of sensors were used:

1. piezoelectric film (PVFT)
2. high frequency miniature hydrophone inserted into the ear canal.
3. Accelerometer placed on various sites of the skin of the neck.

All had advantages. The film sensor would be disposable and cheaper. The hydrophone can always be positioned in the same location, but it is expensive. An accelerometer is less costly than the hydrophone, is not disposable and will require some sort of headband for clinical use. The sensor issue will be resolved over the next few months. An example of the hydrophone placement and the data acquisition and display are depicted below.



The data analysis will be discussed next, suffice it to say the results are repeatable and in a form for conversion to cerebral spinal fluid units of pressure.

The following seven charts depict data recorded from the head in response to vibrational stimuli delivered when the body was upright (low or ambient cerebral spinal fluid condition) and when their body was inverted by a special flip recliner (presumably a condition of increased cerebral spinal fluid). Not that inversion changes the vibratory response as predicted in the model. The two additional charts portray the data acquisition parameters of the developed software analysis system.

External Validity

It is impossible to determine if the vibrational changes observed represent changes in cerebral spinal fluid since there was no direct measurement of the fluid pressure. We are encouraged since there is strong literature that various activities can increase cerebral spinal fluid pressure, one of which is body inversion. It is reported that inverting the body will increase the pressure to about 900 mm H_2O, which is about 700 mm or so above ambient pressure. We are operating on the assumption that body inversion increases pressure, but we do not know to what degree or the time constant of returning to equilibrium.

The question of external validity can be address interns of our fundamental concept of resonance. Lim modeled the resonance of the brain and found it to be a function of the speed of sound in fluid divided by diameter times π multiplied by a constant (boundary condition). Modeling the conductive pathway through the brain in one dimension is equivalent to a closed tube. Resonance of a closed tube is a product of the speech of sound divided by two times the length.

Resonance would also be associated by standing waves in the head when the stimulus wavelength is equal to the brain diameter or some multiple. Under these conditions the wave would be canceled on one side of the head and present at the source side. Perceptually this will result in a lateralized sound image to one side or the other. All subjects reported that some tones n the sequence "jumped" across their heads, suggesting traveling waves. The effect was frequency dependent and would be expected to be related to skull/brain geometry. Although the ear is a very good acoustic analyzer, the phenomena can be directly measured. When standing waves occur little energy should be present at one side of the head in a specific frequency range.

Standing waves, that is incoming waves canceling reflected waves, were measured by modifying the cerebral spinal fluid pressure analysis system. An accelerometer was placed on the driving side of the head and a second accelerometer was placed on the opposite side. Tones were presented in a series and recorded from both sides. Resonance would be expected in the 11 and 22 kHz ranges (both predicted from Lim). Subjects were not inverted in this task

An example of the results of this experiment on one representative subject is depicted below. The frequencies used were selected to encompass the expected second harmonic in the brain resonance (~22 kHz).

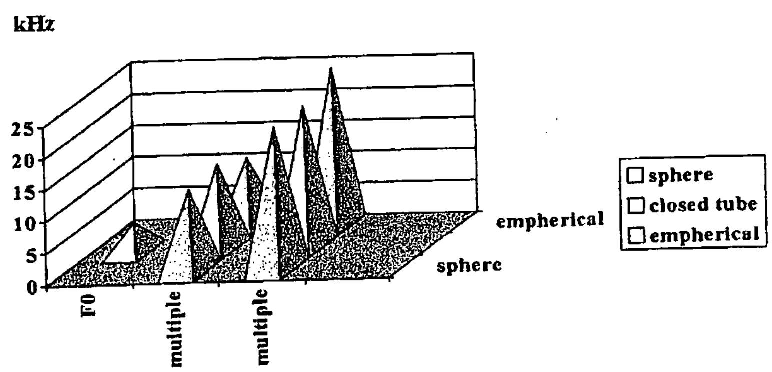
confirming empirically resonance with bone conduction stimulation

Tones to right ear sensor on right ear

Tones to right ear sensor on left ear

When data from six subjects are pooled and summarized the data can be graphically portrayed (see below).

brain resonance predications measurements



Thus it appears that the analysis system accurately determines brain resonance and increases in cerebral spinal fluid will alter the vibrational behavior of the brain as predicted in the modeling.

Research Aims (CSF)

The objective of this project is the development of a non-invasive monitor of intracranial pressure for medical applications. The approach is an indirect one, attempting to use vibration analysis as a reflection of intracranical pressure changes. Center to our approach is to determine brain resonance and develop a digital system that functions in the range of resonance.

1. **Model Analysis**
   a. model cranial vibrations
   b. generate digital simulation
   c. simulate system
   d. design prototype system

2. **System Prototype**
   a. receiver analysis algorithm
   b. implement the stimulus
   c. implement the receiver

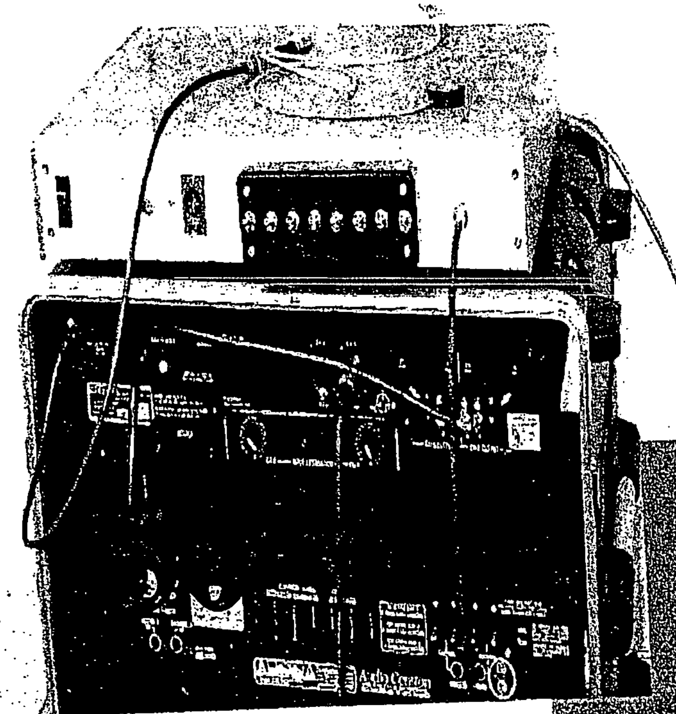
3. **Prototype Evaluation**
   a. perform system evaluation
   b. prepare for clinical trials (code and hardware)

Martin L. Lenhardt, Ph.D., Au.D.

[redacted]

[redacted]

from analog to walkman



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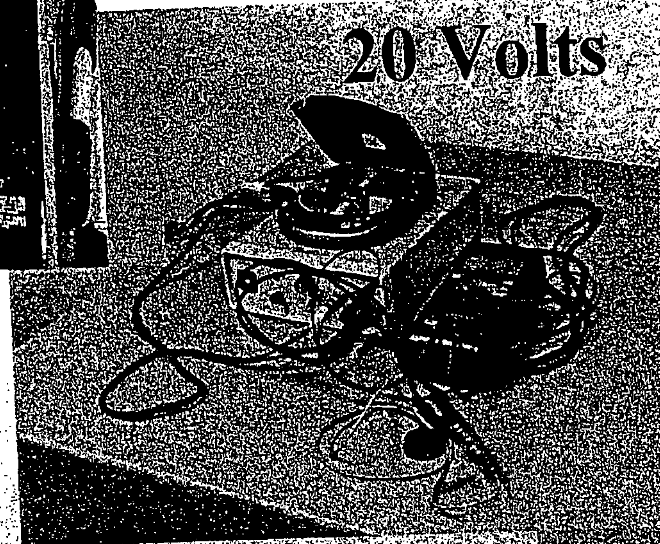
20 Volts



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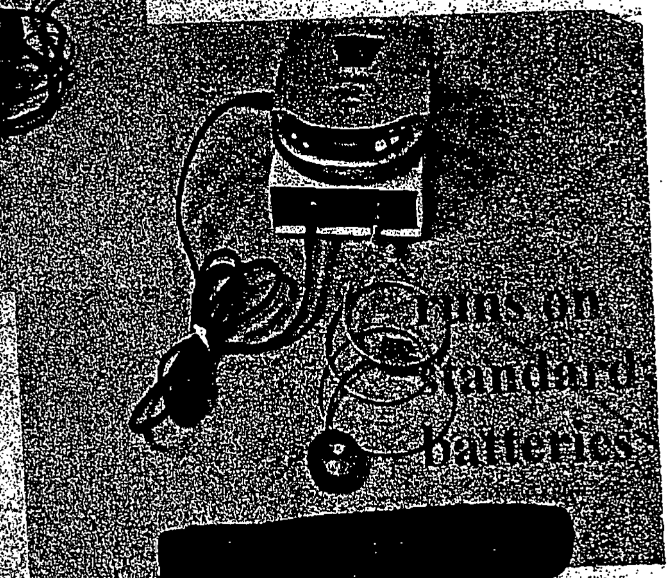
1-2 Volts



runs on standard batteries

[redacted]

Ultra Pitchtm

Sound Technique Systems, LLC

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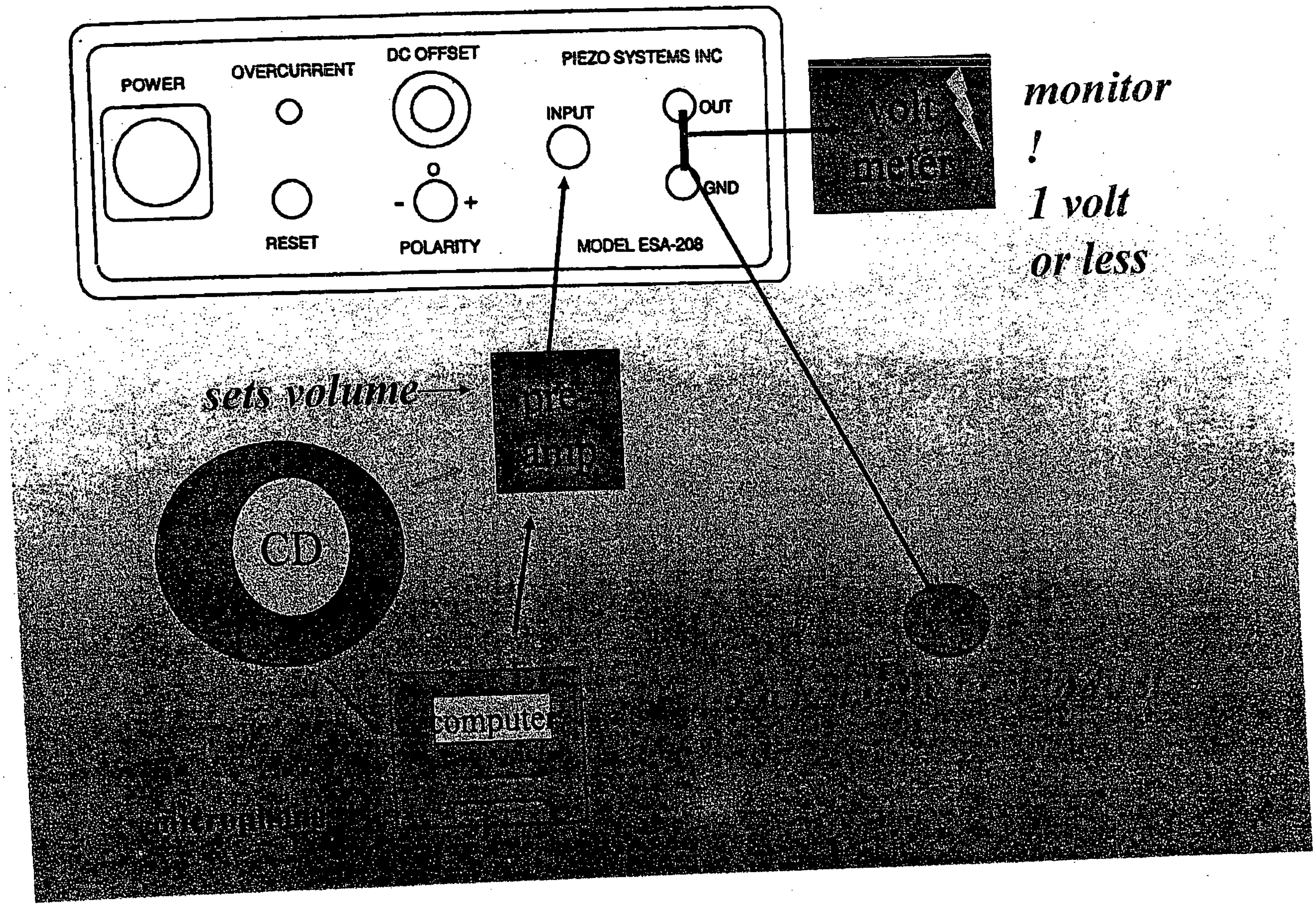
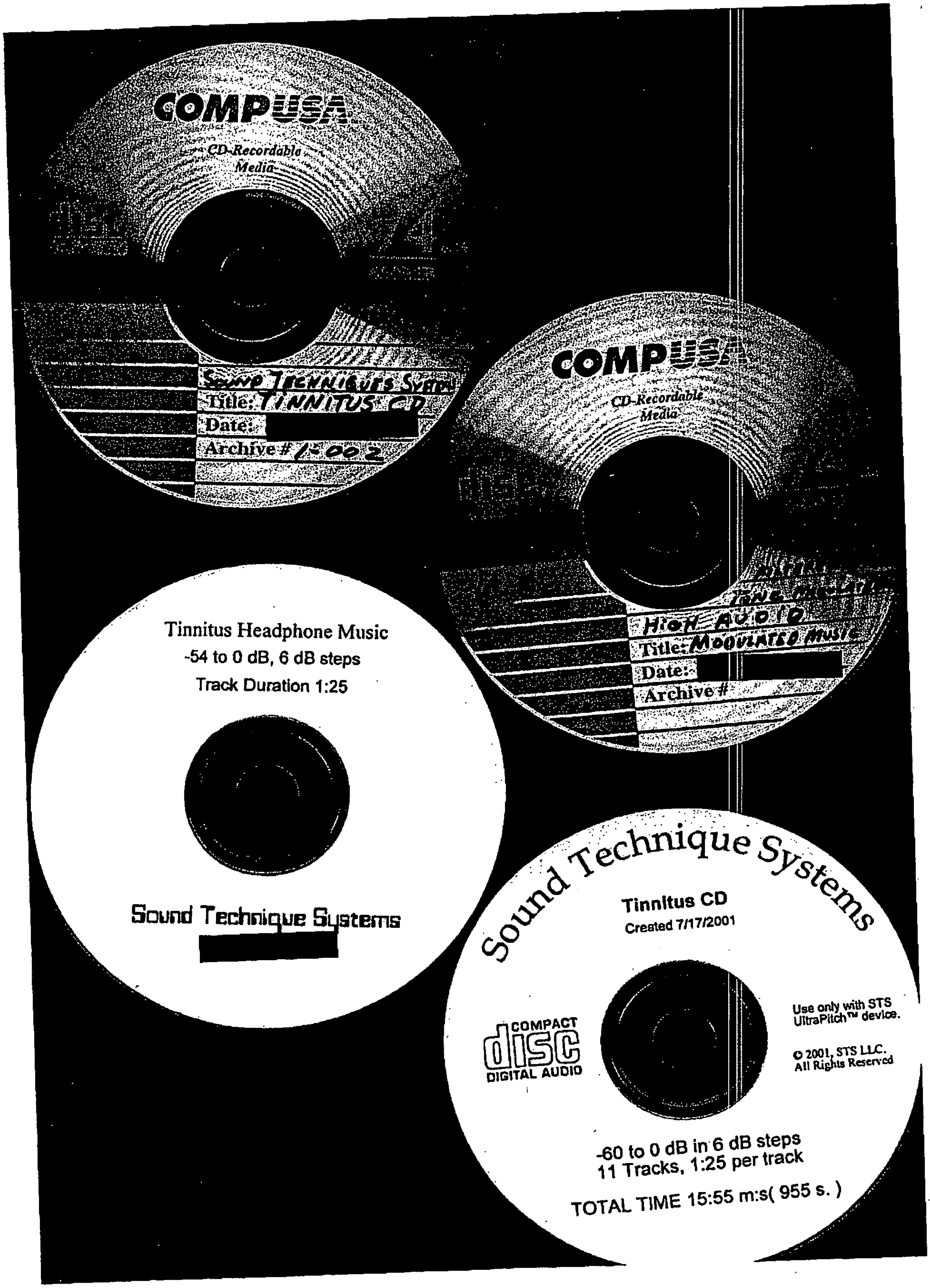
Sound Technique Systems, LLC

MODEL ESA-208 Switching Amplifier with Integral Power Supply

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CD-Recordable Media
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Tinnitus Headphone Music
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-60 to 0 dB in 6 dB steps
11 Tracks, 1:25 per track
TOTAL TIME 15:55 m:s(955 s.)